EXHIBIT A

PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(b)(2).

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TITLE OF THE INVENTION (280 CHARACTERS MAX)

INTERCHANGEABLE REFERENCE FRAMES FOR USE WITH ELECTROMAGNETIC LOCALIZATION

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ENCLOSED APPLICATION PARTS (check all that apply)

X	Specification	Number of Pages	14	☐	Small Entity Statement
X	Drawings	Number of Sheets	5	☐	(Other (Specify)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)

		FILING FEE AMOUNT ($)	
X	A check or money order is enclosed to cover the filing fees.		$160.00
X	The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number 13-0017.		

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No.

[ ] Yes, the name of the U.S. Government agency and the Government contract number are: ____________

Respectfully submitted,

SIGNATURE ____________   DATE November 14, 2002

TYPED or PRINTED NAME Kirk A. Vander Leest   REGISTRATION NO. 34,036

[ ] Additional inventors are being named on separately numbered sheets attached hereto.

USE ONLY FOR A PROVISIONAL APPLICATION FOR PATENT

Attorney Docket No. 14131US01

TITLE

INTERCHANGEABLE REFERENCE FRAMES FOR USE WITH ELECTROMAGNETIC LOCALIZATION

BACKGROUND OF THE INVENTION

[01] In computer assisted surgery, one or more instruments are tracked by a localizing device so that calculations regarding the anatomy can be made or graphics generated. Tracking of the instruments is often accomplished by an optical localizer, for which each instrument is outfitted with an array of emitters, usually light emitting diodes or reflective spheres, and a camera assembly views their positions in space. The pose of emitter array is measured when the camera views the emitters and performs calculations to determine their positions. Another method of tracking utilizes two kinds of electromagnetic sensors: a transmitter that generates an electromagnetic field and one or more receivers that sense the electromagnetic field. The pose of the receiver is measured by a computer using data from the receiver to calculate the positions in the field of the receiver relative to the transmitter. Alternatively, in some electromagnetic localizing systems, multiple transmitters are used.

[02] In electromagnetic systems, there are typically restrictions on the distances apart that a transmitter and receiver must be placed in order to yield accurate relative position information. The transmitter and receiver typically must not be too close to one another (e.g., a few inches) or too far apart (more than about 18 inches). Additionally, the presence of devices that generate electromagnetic fields, such as an electric drill, can cause interference with the accurate functioning of the localizing system. Likewise, the presence of some metals, such as those used in retractors, operating room tables or fluoroscopic C-arms, can cause interference that produces localizing errors. This interference is especially pronounced when the metal is in close proximity to either the transmitter or receiver, or anywhere in between them. This interference can be

minimized by careful placement of the tracking devices relative to one another and to potential sources of interference.

[03] Total knee surgery is a frequently performed orthopaedic procedure intended to replace the articular cartilage of the knee with prosthetic metal and plastic components. In order to properly align these components on the knee, surgeons typically reference anatomic landmarks of the leg. Typically, the center of the hip joint (i.e., the center of the femoral head), the center of the knee, and the center of the ankle joint are all determined (or approximated) by various methods. These methods may involve x-raying the joints, palpating external bony landmarks, measuring the position of the bones, or putting the joints through a range of motion. When x-rays are used, they need to be registered, that is they need to be acquired with the pose of the C-arm measured so that the relative positions of instruments may be correlated to the images.

[04] The goal of knee replacement surgery is to place the total knee components such that the joint centers are collinear, defining what surgeons refer to as the mechanical axis of the knee. Computer assisted techniques can aide in the performance of total knee replacement surgery. One of the steps with which the computer may provide assistance is the identification and location of the joint centers. A difficulty that may be encountered, however, is that these joint centers are separated by distances that may be beyond the working volume of the tracking device. In larger patients, the distance between joints may be over half a meter and the pelvis and the ankle may be over one meter apart. While the working volume of many optical localizers is a one meter diameter sphere, the maximum working distance between an electromagnetic transmitter and receiver is often less than one half meter. Given the distances involved, it may be impossible for receivers to function at both the hip and the ankle. Further, it may not be possible to place the transmitter in a position such that receivers will be able to function at adjacent joints.

[05] Total knee replacement is not the only surgery involving distances that may pose a challenge for some localizing devices. The insertion of a rod in a long bone, an

osteotomy, or any other procedure that requires the tracking of instruments or imaging at both ends of a limb or limb segment, may prove difficult in computer assisted procedures.

BRIEF DESCRIPTION OF SEVERAL VIEWS OF THE DRAWINGS

[06] Figure 1 illustrates a dual fixator according to certain aspects of an embodiment of the present invention.

[07] Figure 2 illustrates a transmitter and a receiver attached to the dual fixator of Figure 1.

[08] Figure 3 illustrates a soft tissue fixator according to certain aspects of an embodiment of the present invention.

[09] Figure 4 illustrates use of the dual fixator and the soft tissue fixator in connection with a total knee surgical procedure.

[10] Figure 5 illustrates use of the dual fixator and the soft tissue fixator in connection with the reduction and fixation of a long bone with a soft fracture.

[11] The foregoing summary, as well as the following detailed description of the preferred embodiments of the present invention, will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the preferred embodiments of the present invention, there is shown in the drawings, embodiments which are presently preferred. It should be understood, however, that the present invention is not limited to the arrangements and instrumentality shown in the attached drawings.

DETAILED DESCRIPTION OF THE INVENTION

[12] Certain aspects of an embodiment of the invention can be used to facilitate the use of electromagnetic tracking in computer assisted total knee replacement surgery. One of the first steps in this procedure is to identify the center of the femoral head relative to a reference frame on the bone. In the illustrated embodiment the reference frame is a dual fixator 10 attached to the distal femur by means of two screws 12 inserted percutaneously into the bone just proximal to the medial epicondyle of the femur. (See Figures 1, 2, and

4). Alternatively, the fixator may be attached to the bone with a single screw and sleeve, a clamp, or any other device that holds it rigidly to the bone. The dual fixator 10 has one mechanism 14 for attaching a transmitter 16, and another mechanism 18 for attaching a receiver 20, and the two mechanisms are in fixed and known positions relative to one another. In the illustrated embodiment, the transmitter attaches to a post with a spring lock, and the receiver attaches with a snap-in receptacle. It will be appreciated that any method of attaching the two sensors may be used without departing from the instant invention so long as the sensors are attached in a rigid and repeatable manner and their positions are accurately known relative to one another.

[13] In order to register images of the femoral head, the location of the C-arm during image acquisition must be determined. Preferably, there is an electromagnetic receiver attached to the C-arm and a transmitter in proximity to the area being imaged. However, later steps in the procedure will require a transmitter on a fixator in the immediate vicinity of the knee, and this will likely involve too great a distance between the transmitter and the C-arm to generate accurate position information. Therefore, a transmitter is attached to the patient in the vicinity of the hip with a soft tissue fixator 22 (see figures 3 and 4). In the illustrated embodiment, the soft tissue fixator 22 comprises a spring-lock post 24 connected to a flexible base 26 that attaches to the patient with Velcro straps 28. Any other means of attaching to the patient in a rigid or non-rigid manner, including bone pins, elastic straps, skin adhesive or, skin staples may be used. Alternatively, the transmitter may be attached to an object near the patient, including the OR table or a structure attached to the table. Any means that holds the transmitter immobile relative to the patient for the duration of image acquisition may be used without departing from the instant invention.

[14] In the preferred embodiment, a receiver is attached to a dual fixator 10 affixed to the distal femur, preferably just proximal to the medial epicondyle; a transmitter is attached to the soft tissue fixator 22 on the proximal thigh; and a receiver 30 is attached to the C-arm 32. (See Figure 4) Alternatively, any combination of sensors may be used as long as the relative position of two adjacent sensors may be determined. First, the

pose of the receiver on the dual fixator 10 on the distal femur is measured relative to the transmitter on the soft tissue fixator 22 on the proximal thigh. Next, images are acquired of the hip and the pose of the C-arm 32 measured relative to the transmitter on the soft tissue fixator 22. Next, the pose of the receiver on dual fixator 10 the distal end of the femur is measured relative to the transmitter on the soft tissue fixator 22 a second time.

[15] The first and second poses measured for the distal receiver relative to the transmitter are compared, and if they are not essentially identical, it should be assumed that there was motion of the soft tissue fixator and that the accuracy of the pose of the C-arm is in doubt. This could be due to the transmitter being bumped by the user or the C-arm, by patient movement, or by unstable attachment of the soft tissue fixator to the patient. In this case, an error will be indicated to the user, and the process should be repeated after verifying the correct, secure placement of the soft tissue fixator. If the first and second measured poses of the distal receiver relative to the transmitter are essentially identical, then it is assumed that there was no motion of the soft tissue fixator relative to the bone and that the image is valid.

[16] After images are acquired, the receiver may be removed from the dual fixator 10 and the transmitter attached to the dual fixator. The relationship of the transmitter and receiver when attached to the dual fixator 10 is preferably known ahead of time from manufacture of the fixator, but could also be determined from a calibration step using a second transmitter and receiver. Mathematical methods well known in the art are used to calculate the pose of the C-arm relative to the transmitter on the dual fixator. Preferably, this process is repeated for each image acquired of the hip. Alternatively, the steps of measuring, re-measuring, and comparing poses of the distal receiver may be performed once with multiple images acquired and C-arm poses calculated at one time.

[17] Additionally, this technique may be applied to the acquisition of registered images of body parts other than the hip. During the total knee procedure, registered images of the ankle may be obtained by placing a fixator with an attached receiver at the proximal tibia and the soft tissue fixator with an attached transmitter on the calf. In a manner similar to the imaging of the hip: the pose of the affixed receiver is measured, the C-arm

acquires the 2D images of the ankle, the pose of the affixed receiver is measured again, and the receiver poses are compared. The receiver may then be removed from the dual fixator and replaced by the transmitter. Calculations may be performed to find the pose of each image relative to the transmitter or receiver. Alternatively, this process for acquiring images may be employed any time it is desired to obtain registered images from an area of the body that is remote from the reference fixator.

[18] In the preferred embodiment, the pose measurements are made sequentially because the C-arm may interfere with the measurement of the pose of the distal receiver. In this case, the measurements of the distal receiver are made with the C-arm a sufficient distance away from the transmitter and distal receiver. However, if interference from the C-arm is not a problem, the poses of the C-arm and the distal receiver may be made simultaneously without the need to compare a first and second measurement of the distal receiver. Further, while the invention has been described for use during acquisition of 2D fluoroscopic images, it may apply equally as well to acquisition of 3D x-ray images or images derived from other modalities.

[19] The next step in the preferred embodiment of the total knee procedure is the acquisition of a registered image of the knee. Preferably, the transmitter is placed on the dual fixator at the distal femur and a receiver is placed on the dual fixator on the proximal tibia. The pose of the receiver on the proximal tibia is measured relative to the transmitter on the distal femur. Then, C-arm images are acquired of the knee, including the proximal femur and distal tibia. Next, the pose of the receiver is again measured and compared to the previous pose measurement and an error indicated if there is a significant discrepancy. If there is no error, calculations are made to register the images relative to the receiver on the proximal tibia and to the transmitter on the distal femur. Alternatively, if the tracking system permits, the poses of the receiver and the C-arm may be measured simultaneously and there will be no need for the comparison of two pose measurements. Additionally, separate images of the distal femur and proximal tibia could be acquired and registered independently to a transmitter on each bone.

[20] Once the images are acquired and registered, they may be used to identify the joint centers. The center of the femoral head may be specified by identifying points on the x-ray image that lie in the center of the circular femoral head. Alternatively, templates or other graphic or numerical techniques may be used to accurately find the center of the femoral head. Similarly, landmarks visible in the x-rays are used to enable the surgeon to identify and mark the center of the knee and ankle joints. Alternatively, other non-imaging methods may be used to determine the center of any of the joints. For example, the femur may be moved through a range of motion at the hip joint, while the system tracks the pose of a sensor mounted to the femur, and the joint center is defined as the center of the sphere segment defined by sensor motion. Similarly, kinematic methods may be used to identify the centers of the knee or ankle, or the surgeon may touch external landmarks with a probe (e.g., medial and lateral malleoulus of the ankle) and the joint centers are calculated from these.

[21] Once the joint centers are identified and the mechanical axis of the leg defined, cuts in the distal femur and proximal tibia may be defined and executed to accommodate the total knee components. These are preferably performed with a transmitter placed on the fixator of the bone being resected and the receiver placed in the cutting block or other instrument being employed. In an alternative embodiment, kinematic analysis of the knee can be performed with a transmitter on the femur and a receiver on the tibia, or vice versa. The surgeon places the knee through a range of motion and applies stresses to the joint while the tracking device records accurate position data for both femur and tibia. This data can be analyzed in order to better define depths of cuts, sizing of components, need for soft tissue adjustments, and the optimum positioning and orientation of the components.

[22] An alternative example of a surgery involving large distances between tracking sensors is the reduction and fixation of a long bone with a shaft fracture. (See Figure 5) In one step of the procedure to place an intramedullary rod down a fractured femur, a long reduction tool 34 is inserted down the shaft of the femur for the purpose of bridging the fracture site and aligning the fragments. As the tip of the reduction tool is being first

inserted into the end of the bone, the distance between the distal fragment and the handle of the reduction tool (the part that typically would attach to a tracking sensor) can be over twice the length of the femur.

[23] In order to track the reduction tool relative to the distal bone fragment, a dual fixator 10 is attached to the fragment. A transmitter is attached to the fixator and x-ray images of the fragment are acquired. Next, the transmitter is removed from the dual fixator and replaced by a receiver. The transmitter is affixed to the soft tissue fixator 22 which is attached to the proximal thigh, near the insertion site of the reduction tool 34. It should be noted that the transmitter is not, and need not be, attached rigidly to any structure or bone. A second receiver is then attached to the reduction tool 32 which is inserted into the femur. By simultaneously measuring the poses of the receiver on the distal fragment and the reduction tool relative to the transmitter, the pose of the reduction tool relative to the fragment can easily be calculated by methods well known in the art. This information may then be displayed to the surgeon to guide the insertion of the tool. Alternatively, additional receivers could be attached to the proximal and other fracture fragments, and the fragments included in the x-ray images, to track their positions as well.

[24] While the forgoing describes techniques and apparatus for accommodating tracking over relatively large distances in total knee replacement and shaft fracture repair surgeries, it should be understood that these techniques and apparatus apply equally well to any procedure which involve similar distances. Additionally, if still greater distances than these are involved, they may accommodated with additional transmitters and/or receivers spaced apart over the additional distance and in communication with one another. Even without additional sensors, the longer distances may be accommodated by moving a transmitter and receiver pair sequentially among a series of rigidly placed dual fixators.

[25] Further, while the forgoing describes the use of an electromagnetic transmitter and sensor, it must be noted that any tracking system may benefit from these techniques

if the tracking sensors employed differ in any way, and there is any situational reason to use one sensor in preference of another.

[26] While the invention has been described with reference to a preferred embodiment, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the scope of the invention. In addition, many modifications may be made to adapt a particular situation or material to the teachings of the invention without departing from its scope. Therefore, it is intended that the invention not be limited to the particular embodiment disclosed, but that the invention will include all embodiments falling within the scope of the appended claims.

CLAIMS

1. A system for localizing instruments relative to a patient's bone comprising;

an electromagnetic localizing device with an electromagnetic field transmitter and an electromagnetic field receiver;

a fixator for attaching to bone, said fixator being capable of attaching a transmitter and receiver in a fixed and known position relative to one another;

a first surgical instrument with an attached transmitter;

a second surgical instrument with an attached receiver;

means for determining the pose of the first surgical instrument relative to the fixator with an attached transmitter;

means for determining the pose of the second surgical instrument relative to the fixator with an attached receiver;

means for calculating the pose of the first surgical instrument relative to the second surgical instrument.

2. A method for extending the spatial operating range of an electromagnetic localizing system comprising the steps of:

providing an electromagnetic localizing device with an electromagnetic transmitter and receiver;

providing a first surgical instrument with an attached receiver;

providing a second surgical instrument with an attached transmitter;

providing a fixator to which a receiver and a transmitter attach;

calculating the position of a receiver attached to the fixator relative to a transmitter attached to the fixator;

attaching a receiver to the fixator;

determining the pose of the first surgical instrument relative to the receiver attached to the fixator;

removing the receiver from the fixator;

attaching a transmitter to the fixator;

determining the pose of the second surgical instrument relative to the transmitter attached to the fixator;

calculating the pose of the first surgical instrument relative to the second.

3. A fixator for use with an electromagnetic tracking device comprising:

means for attaching to an electromagnetic field transmitter;

means for attaching to an electromagnetic field receiver in a fixed and known relationship to the means for attaching the transmitter;

wherein either the transmitter or receiver may be attached to the fixator to serve as a reference relative to other receivers or transmitters.

4. The fixator of claim 3 further comprising a means for attaching to patient's bone.

5. A method for tracking surgical instruments relative to a first and second anatomical site comprising the steps of:

providing an electromagnetic localizing device with a transmitter and receiver;

providing a first and second surgical instrument, each with an attached receiver;

providing a first fixator with means for attaching a receiver;

providing a second fixator with means for attaching a receiver and means for attaching a transmitter;

placing the first fixator with an attached transmitter in proximity to the first anatomical site;

determining the pose of the surgical instrument relative to the transmitter;

placing the second fixator with an attached receiver in proximity to the second anatomical site;

determining the relationship between the first and second fixator;

attaching a transmitter to the second fixator;

determining the pose of the second surgical instrument relative to the second fixator.

6. The method of claim 5 further comprising the step of calculating the pose of the second surgical instrument relative to the first fixator.

7. The method of claim 5 wherein the second surgical instrument is the first surgical instrument.

8. A method for providing computer assistance during a surgical procedure comprising the steps of:

providing an electromagnetic localizing device with a transmitter and two or more receivers;

providing a first and second surgical instrument, each with an attached receiver;

positioning the transmitter approximately midway between the surgical instruments;

determining the poses of the receivers relative to the transmitter;

calculating the pose of the first instrument relative to the second instrument;

wherein the relative instrument positions are displayed to the surgeon during surgery.

9. The method of claim 8 wherein the transmitter is positioned by a fixator that attaches to the patient's bone.

10. The method of claim 8 wherein the transmitter is positioned by a fixator that attaches to the patient by means of a belt or strap.

11. The method of claim 8 wherein the first or second surgical instrument attaches rigidly to the patient's bone.

12. A method for acquiring x-ray images of a patient's first anatomical site relative to an second anatomical site, comprising the steps:

providing an electromagnetic localizing device with an electromagnetic transmitter and receiver;

placing a first fixator in proximity to the first anatomical site;

attaching a second fixator to the bone at the second anatomical site;

attaching the receiver to the first fixator;

attaching the transmitter to the second fixator;

determining a first pose of the receiver relative to the transmitter;

acquiring an image of the first anatomical site, said image registered relative to the transmitter;

determining a second pose of the receiver relative to the transmitter;

comparing the first pose to the second pose and indicating an error if the poses differ by more than a predetermined value;

calculating the registration of the image relative to the receiver;

wherein the registered image may be located relative to the receiver at a distance greater than the maximum distance at which the receiver and transmitter may operate.

13. The method of claim 12 further comprising the steps of:

providing a surgical instrument with a transmitter;

determining the pose of the surgical instrument relative to the receiver;

calculating the pose of the surgical instrument relative to the x-ray image.

14. The method of claim 12 wherein a transmitter attaches to the first fixator in a fixed and known relationship to the receiver and further comprising the steps of:

removing the receiver from the first fixator;

attaching a transmitter to the first fixator;

providing a surgical instrument with a receiver;

determining the pose of the surgical instrument relative to the transmitter;
calculating the pose of the surgical instrument relative to the x-ray image.

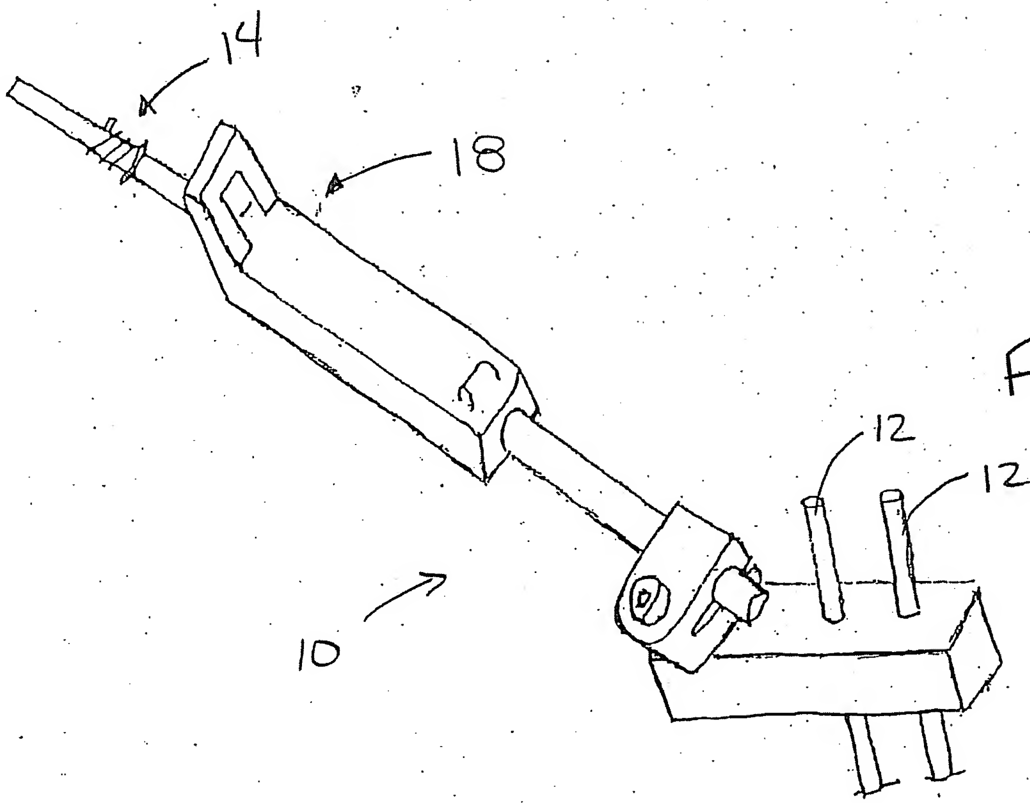

FIG. 1

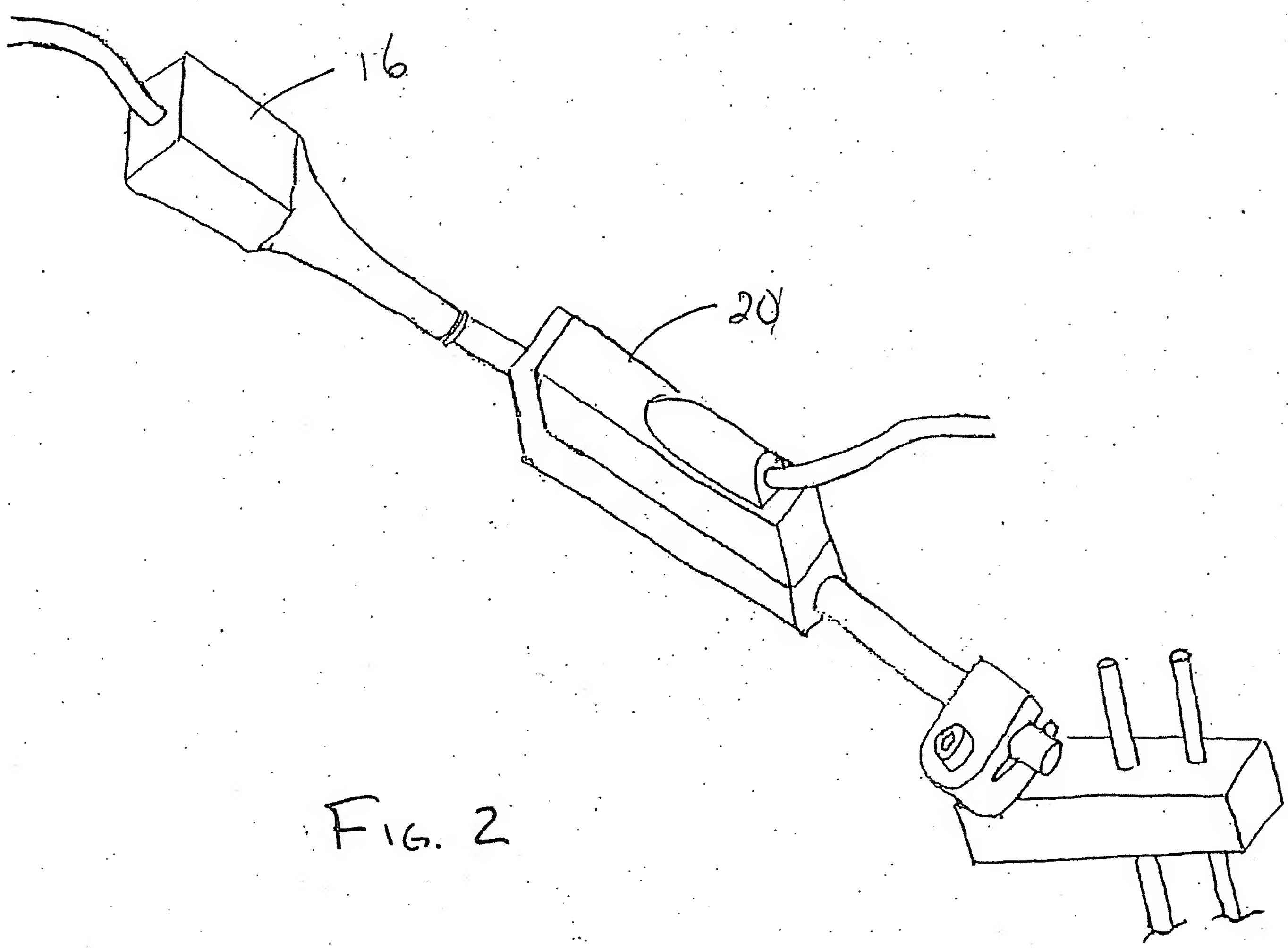

FIG. 2

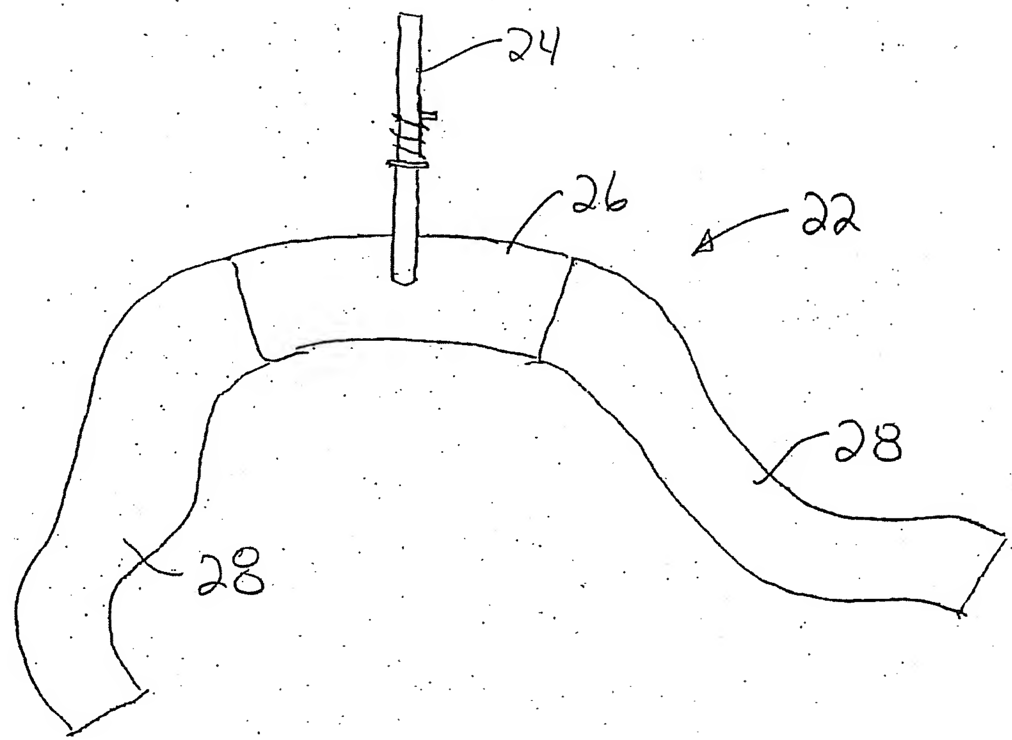

FIG. 3

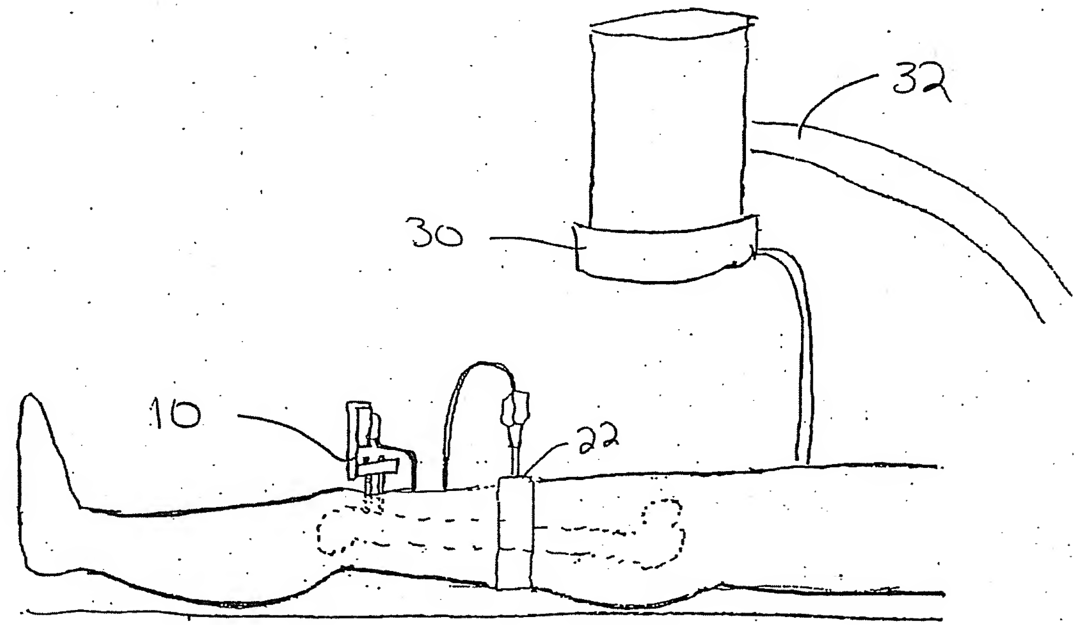

FIG. 4

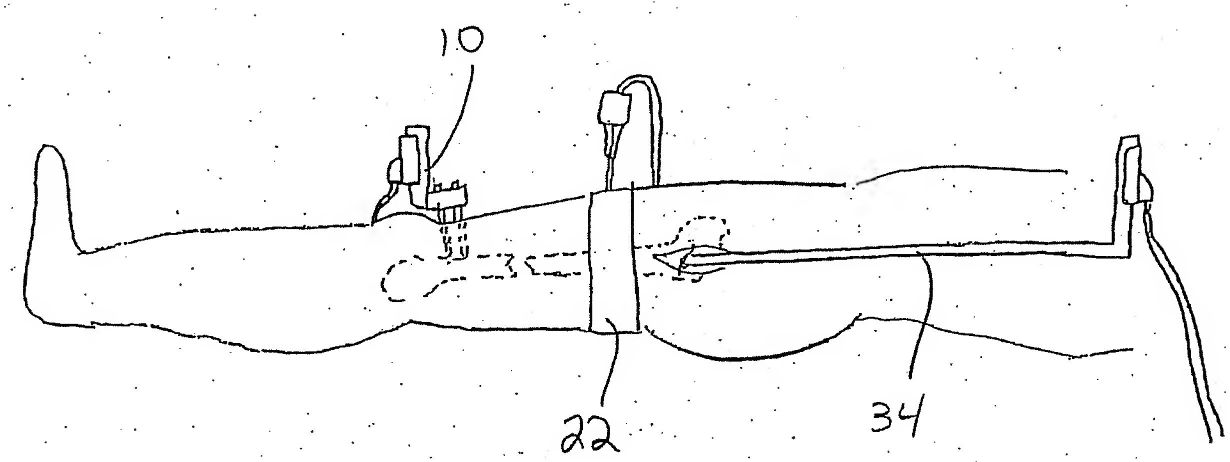

FIG. 5